REMARKS

Upon entry of this amendment, claims 10-39 will be pending in this application. By this Amendment, claims 1-9 are cancelled, and new claims 10-39 are added. Reconsideration of the merits of the application in light of the amendment above and the remarks that follow is respectfully requested.

No new matter has been added as a result of the amendment. Claims 10-39 correspond to claims 1-30 of parent application (09/270,540), which is now abandoned. As such, the remarks below address the rejection in the Office Action mailed June 20, 2000 in the parent application. Applicants assert that the remarks below also address the Office Action mailed July 5, 2001 in the present application.

Hakim et al.

In the Office Action mailed June 20, 2000 in the parent application, claims 1, 4, 7, 10-14, and 16-20 (current claims 10, 13, 16, 19-23, and 25-29, respectively) stood rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Hakim et al. 4,608,992. Claims 2 and 8 (current claims 11 and 17, respectively) stood rejected under 35 U.S.C. 103(a) as being unpatentable over Hakim et al 4,608,992.

Specifically, with response to the '102 rejection under Hakim et al, the Examiner has state that Hakim teaches a locator tool and an indicator too 74, a system for aligning the locator tool with a subcuataneously implanted shunt valve wherein the implanted valve physically protrudes into a recess in the locator tool thus aligning the two components. Specifically, the Examiner has state that Hakim teaches a deck 10, a visual arrow indicator 74 on the deck and a cylindrical tube with deck attached. Further, the Examiner asserts that the deck has a locator central opening 26 extending entirely through the deck. The applicant respectfully disagrees.

Hakim et al is a device for measuring physiopathological parameters for example, body fluid pressure, sugar level, venous pressure (Col. 1, lines 7-9, col.2 lines 40-45 and col. 6, lines 53-57). In particular, Hakim et al. discloses a manometer 12 that forms a palpable protrusion 24 on

the surface of the skin over which a mating recess 26 in a viewer 10 fits. (Col. 3, lines 60-62, col. 4, lines 5-7). The viewer device 10 externally detects and visually communicates the orientation of one or more magnets in an implanted device that measures physiopathological parameters.

By contrast, instant claim 10 is directed to:

"A locator tool for deterring the orientation of a medical device with an implanted adjustable valve, the medical device having a tactile physical characteristic that indicates a specific orientation of the implanted adjustable valve of the medical device...". (Emphasis added).

Present claim 13 is directed to:

"A system for inidicating the current setting of an implanted adjustable valve with a tactile physical characteristic that indicates a specific orientation of the valve and a magnet indicating a current setting of the valve:..."(Emphasis added)

Instant claim 16 is directed to:

" A method for orienting a medical device with an implanted adjustable valve with a tactile physical characteristic that indicates a specific orientation of the valve...". (Emphasis added)

Present claim 11 is directed to:

"An indicator tool for indicating the current setting of an implanted adjustable valve with a tactile physical characteristic that indicates a specific orientation of the valve..."(Emphasis added)

Instant claim 17 is directed to:

"A method of indicating the current setting of an implanted adjustable valve with a tactile physical characteristic that indicates a specific orientation of the valve...". (Emphasis added)

A common thread in the claims above is tool or method thereof that works with "an implanted adjustable valve." The implantable valves in the above claims are "one-way flow control valves controlling the flow of Cerebral Spinal Fluid (CSF) out of a brain ventricle and preventing backflow of the fluid into the brain ventricle." (Application, page 1, lines 9-10) These one-way flow control valves include a mechanism to control fluid flow through the valve. (Application, page 3, line 3, erroneously listed as line "45). The mechanism includes a magnet embedded within a base (Id at lines 3-4). Rotating the base changes the internal configuration of the mechanism. (Id at lines 4-5). Changing the internal configuration of the configuration of the mechanism produces a variety of pressure or flow characteristics for the valve. (Id at lines 5-7). The locator device of the claimed inventions is s locator device for locating one-way flow control valves ad described above.

There is no teaching or suggestion Hakim et al. for a device that has an implanted adjustable valve and more particularly for a device "that determines the orientation of a medical device with an implanted adjustable valve... that indicates a specific orientation of the implanted adjustable valve of the medical device" as is claimed by the present claim 1. Although valves are mentioned in Hakim et al. (col. 5, lines 17-24), the valves mentioned are to open and close the manometer to provide a pressure difference across the manometer, not to provide an one-way flow control valve to control the flow of body fluids through the valve as is the case with the presently claimed invention.

Since Hakim et al. does not teach or suggest a device or method for indicating the orientation of an implantable valve, it is respectfully submitted that Hakim et al. does not anticipate the claimed invention. Further, since Hakim et al. deals exclusively with a device to determine and communicate physiopathological parameters and does not even mention, much less teach or suggest, a one-way fluid control valve, it is also respectfully submitted that Hakim et al. does not render the present invention obvious. Therefore, the Examiner is respectfully request to recondiser his '102 rejections of claims 1, 4, 7, 10-14 and 16-20 and his '103 rejections of claims 2 and 8.

Hooven and Hakim in light of Hooven

In the Office Action mailed June 20, 2000 in the parent application, claims 3 and 15 (current claims 12 and 24, respectively) stood rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Hooven 4, 676,772 and claims 5, 6, 9 and 21-30 (current claims 14, 15, 17, and 30-39, respectively) stood rejected under 35 U.S.C. 103(a) as being unpatentable over Hakim et al. 4,608,992 in view of Hooven 4,676,772. With respect to the '103 rejection on Hooven '772 alone, the Examiner has stated that "Hooven teaches all the claimed subject matter except for the adjustment tool being connectable to the locator tool." The application respectfully disagrees.

Hooven '772 teaches "a position sensor for non-invasively sensing the position of a magnetic wrench in a non-invasively adjustable intracranial pressure relief valve" (col. 1, lines 7-10) which is a similar subject matter area to the presently claimed invention. However, Hooven '772 does not teach all the claimed subject matter of the presently claimed invention. Claim 12 recites in part:

> "means for coupling the indicator of an orientation of the valve with the tactile physical characteristic of the valve to indicate a specific orientation of the valve, the means including a deck having an outer edge and a locator central opening extending entirely through the deck, the locator central opening having an outer edge defining the locator central opening, the outer edge of the locator central opening corresponding in shape to the outer edge of the tactile physical characteristic, wherein the locator central opening is capable of overlaying and conforming to the tactile physical characteristic so that the space between the locator central opening and the tactile physical characterisitic is minimized to indicate alignment between the locator central opening the tactile physical characteristic.".
> (Emphasis added)

There is no "deck" in Hooven '772 with "a locator central opening extending entirely through the deck'. Consequently, Hooven '772 has no "locator central opening having an outer edge defining the locator central opening". Further, Hooven'772 has no "outer edge of the locator central opening corresponding in shape to the outer edge of the tactile physical characteristic, wherein the locator central opening is capable of overlaying and conforming to the tactile physical characteristic so that the space between the locator central opening and the tactile

physical characteristic is minimized to indicate alignment between the locator central opening and the tactile physical characteristic...".
(Emphasis added) It is respectfully submitted that Hooven '772 does not have or teach "all the claimed subject matter" as alleged by the Examiner.

Nor would it be obvious to take the device of Hooven '772 and modify it to become the device of claim 12. Hooven '772 teaches a position indicator 80 having "a pair of alignment tongs 97 and 98" (col.7, lines 19-21) to align the position indicator 80 with the catheters running into and out of the valve 12 (col. 7, lines 28-31). These tongs are described in Hooven '772 as:

> "alignment tongs 97 and 98 [are] affixed to the undersurface of the indicator housing 90. Each tong comprises a pair of vertically disposed downwardly depending table 100-101 and 102-103 defining channels therebetween. The tongs are located at points diametrically opposite one another on the indicator housing such that the channels formed between members 100 and 101 and 102 and 103 are collinear. The channels formed between tabs 100-103 are sufficient width as to receive the subcutaneously implanted catheters 17 and 22 together with the scalp 25 overlying each. Preferably, the edge of teach tab is rounded to avoid the possibility of damage to the patient's scalp. In this manner, the alignment tongs 97 and 98 enable the position indicator 80 to be repeatably positioned over the implanted valve 12 and thereby maintain a constant orientation relative thereto." (Col. 7, lines 20-36)

Thus, the tabs 100-101 and 102-103 extend downward on opposite sides of the position indicator 80 and form a channel between tables 100-101 and tabs 102-103. These tabs "straddle" the catheters 17, 22, respectively, to orient the position indicator 80 with the valve 12.

This is in contradistinction to claim 12, where the deck has "a locator central opening extending entirely through the deck, the locator central opening having an outer edge defining the locator central opening, the outer edge of the locator central opening corresponding in shape to the outer edge of the tactile physical characteristic, wherein the locator central opening is capable of overlaying and conforming to the physical characteristic so that the space between the locator central opening and the tactile physical characteristic is minimized to indicate alignment between the locator central opening and the tactile physical characteristic...," So, instead of tongs straddling catheters, the presently claimed invention has a central opening that receives the valve

and allows the invention to be aligned with the valve by minimizing the space between the outer edge of the central opening and the valve.

To modify the device of Hooven '772 to become the device of claim 12 would require at least taking the "disk shaped indicator plate 81" (col. 6, lines 39-41), forming " a locator central opening extending entirely through the {indicator plate 81}", with the locator central opening having its "outer edge... corresponding in shape of the outer edge of the tactile physical characteristic." In contradistinction to the Hooven '772 device, this allows the locator central opening to overlay and conform to the tactile physical characteristic of the valve so that the space between the locator central opening and the tactile physical characteristic is minimized to indicate alignment between the locator central opening and the tactile physical characteristic of the valve. In view of the foregoing, the claim 12 is completely different in form and function from the Hooven '772 device. As a result, claim 12 and its dependent claim 24 are neither anticipated by nor obvious over the Hooven '772 device.

Nor does the combination of Hakim et al. and Hooven '772 anticipate or render obvious the presently claimed invention of claims 14, 15, 18 and 30-39. Claims 14, 15, and 18, the independent claims of the rejected group, all claim the deck structure with the locator central opening that corresponds in shape to the outer edge of the tactile physical characteristics of the valve as described immediately above. Neither Hakim et al. nor Hooven '772 teach or suggest a device having such claimed characteristics and therefore able to locate a valve the way the presently claimed invention does. Since neither reference, singly or in combination, teaches or suggests the present invention and in fact differs in both form and function from the presently claimed invention, it is respectfully submitted that claims 14, 15, 18 and 30-39 are patentably distinct from the claimed references. The Examiner is therefore respectfully request to reconsider his 103 rejection and allow these claims.

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In view of the foregoing amendments, it is believed that the application is now in condition for allowance and notice of same is respectfully requested.

Respectfully submitted,

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